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October 11, 2005

Honorable Gregory M. Sleet
United States District Court for the District of Delaware
J. Caleb Boggs Federal Building
844 N. King Street, Lockbox 18
Wilmington, DE 19801

Re: *Enzon Pharmaceuticals, Inc. v. PhoenixPharmacologics, Inc.*
C.A. No. 04-1285-GMS – Teleconference

Dear Judge Sleet:

The Court should deny Enzon's request for leave to file its proposed summary judgment motions.

With respect to Enzon's pursuit of summary adjudication that it is the sole owner of the 738 Patent, the motion that Enzon proposes is inconsistent with facts of record. Indeed, the undisputed facts reveal the existence of claimed inventions that were *not* invented at Enzon. Thus, summary judgment that Enzon is the sole owner of the patent would be improper.

With respect to Enzon's proposed motion for summary judgment on Phoenix's defenses, the few facts that Enzon identifies in its letter brief would not support the relief that Enzon seeks and, moreover, are in error, thus precluding summary judgment.

Background

This is a civil action initiated by Enzon, pursuant to 35 U.S.C. § 256, to change the inventorship of U.S. Patent 6,183,738 B1 ("the 738 Patent") and to compel Phoenix to assign to Enzon all the rights in the patent that Phoenix received by assignment from Dr. Mike Clark. Dr. Clark is Phoenix's co-founder and the sole inventor named on the 738 Patent. Enzon amended its Complaint in 2005 to additionally allege that Phoenix has unjustly enriched itself at Enzon's expense by, for example, receiving the 738 Patent.

The 738 Patent is directed to chemical compounds that can be used, for example, to treat certain types of cancer. The compounds disclosed and claimed in the patent generally include three components: (1) a specific type of protein, known as arginine

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deiminase (“ADI”), that can be derived from certain microorganisms; (2) a polymer, known as polyethylene glycol (“PEG”); and (3) a linker that is positioned between the ADI component and the PEG component to connect them. The issued claims of the 738 patent are directed to compounds of this type that include specific types of linkers, specific sizes of PEG polymers, and/or ADI from specified microorganisms.

In 1994, Enzon hired Dr. Clark as associate vice president of research. Dr. Clark supervised numerous research projects at the company, including a project that involved linking ADI to PEG. Only two years later, however, Enzon implemented a reduction-in-force that resulted in the dismissal of Dr. Clark. Following Dr. Clark’s dismissal, he joined the Ludwig Institute for Cancer Research and continued researching ADI-PEG as a potential anti-cancer treatment. Although Enzon exchanged a number of letters with Dr. Clark and the Ludwig Institute during 1996 regarding the extent to which Dr. Clark would be able to conduct such research in view of obligations that he was alleged to owe to Enzon, no agreement was ultimately reached on this issue, and Enzon did not raise it again with Dr. Clark or any company or other organization with which he was associated. Despite knowing that Dr. Clark was developing PEG-ADI with the Ludwig Institute, Enzon never pursued legal action to prevent Dr. Clark’s continued research of PEG-ADI, and never pursued legal action asserting that Dr. Clark misappropriated Enzon’s trade secrets.

At the Ludwig Institute, Dr. Clark made several discoveries. In late 1996, based on the success of his research at the Ludwig Institute, Dr. Clark formed Phoenix to further develop the ADI-PEG molecules that he had identified while at the Institute. In 1997, Dr. Clark filed the first patent application upon which the 738 Patent is based, and assigned it to Phoenix. The patent issued in February, 2001. Phoenix’s development efforts included conducting human clinical trials of its ADI-PEG compound. It was not until after Phoenix’s clinical trial results were published, and Enzon realized how far behind it was in developing a therapeutic composition based on ADI, that Enzon filed the present suit in September 2004. It did not amend its Complaint to assert an unjust enrichment count until July 2005 – nine years after Enzon corresponded with the Ludwig Institute about Dr. Clark’s work and four years after the 738 Patent issued.

Law & Argument

Summary judgment is proper if it is shown that there is no genuine issue as to any material fact and that the moving party is entitled to a judgment as a matter of law. *Celotex Corp. v. Catrett*, 477 U.S. 317, 322 (1986); *Chimie v. PPG Indus. Inc.*, 402 F.3d 1371, 1376 (Fed. Cir. 2005). In reviewing the underlying record in this litigation, the Court “must view the evidence in a light most favorable to the nonmovant and draw all reasonable inferences in its favor, and must resolve all doubt over factual issues in favor of the party opposing summary judgment.” *SRI Int’l v. Matsushita Elec. Corp.*, 775 F.2d 1107, 1116 (Fed. Cir. 1985) (citations omitted). To successfully oppose the summary judgment motion that Enzon’s proposes to file, Phoenix need only come “forward with

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sufficient evidence to demonstrate the existence of a ‘genuine issue’ of material fact for trial,” *i.e.*, a fact issue upon which a reasonable jury could return a verdict for Phoenix. *A.B. Chance Co. v. RTE Corp.*, 854 F.2d 1307, 1312 (Fed Cir. 1998) (citing *Anderson v. Liberty Lobby, Inc.*, 477 U.S. 242, 248-49 (1986)).

The issuance of a patent creates a presumption that its named inventor is the true and only inventor. *Hess v. Advanced Cardiovascular Sys.*, 106 F.3d 976, 980 (Fed. Cir. 1997). To rebut this presumption, a district court must find clear and convincing evidence that the alleged unnamed inventor was in fact an inventor before correcting inventorship under 35 U.S.C. § 256. *Pannu v. Iolab Corp.*, 155 F.3d 1344, 1350 (Fed. Cir. 1998).

To be an inventor, one must make a significant contribution to the conception of one or more claims of the patent. *Fina Oil & Chem. Co. v. Ewen*, 123 F.3d 1466, 1473 (Fed. Cir. 1997). Conception, in turn, is the "formation in the mind of the inventor, of a definite and permanent idea of the complete and operative invention, as it is hereafter to be applied in practice." *Amgen, Inc. v. Chugai Pharm. Co.*, 927 F.2d 1200, 1206 (Fed. Cir. 1991) (quoting *Hybritech, Inc. v. Monoclonal Antibodies, Inc.*, 802 F.2d 1367, 1376 (Fed. Cir. 1986)). "Conception must include every feature or limitation of the claimed invention." *Slip Track Sys., Inc. v. Metal-Lite, Inc.*, 304 F.3d 1256, 1263 (Fed. Cir. 2002).

The Court Should Deny Enzon Leave To File Its “Sole Ownership” Motion Because There Is A Genuine Factual Dispute As To Whether All Of The Inventions Claimed In The 738 Patent Were Conceived At Enzon

The Court should deny Enzon’s request to file its proposed motion seeking sole ownership of the 738 Patent because genuine issues of material fact exist as to whether or not Enzon employees conceived each of the inventions recited in the 738 Patent claims.

Although Enzon must show that its employees conceived every feature of the claimed inventions to prevail with respect to its proposed motion, the evidence of record reveals a genuine factual dispute as to whether or not the claimed inventions were conceived solely by Enzon employees. Indeed, the evidence of record indicates that the claimed inventions were *not* conceived solely by Enzon employees. For example, although the claims of the 738 Patent are directed to ADI-PEG compounds in which the linking group between the ADI component and the PEG component is, *inter alia*, a carbohydrate or epoxy group (Exhibit 1 hereto at columns 19-20), there is no evidence of record indicating that any Enzon employee ever conceived ADI-PEG compounds including such linking groups. In fact, the available evidence is directly to the contrary. For example, the invention record that Enzon submitted with its letter brief identifies five types of linkers¹ none of which are the carbohydrate or epoxy linking groups that are

¹ The identified linkers are those corresponding to the “SC,” “Flan,” “X-US,” “pi9,” and “Pi-13” groups (Exhibit A to Enzon’s letter brief at E016070).

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recited in the 738 Patent claims. Moreover, Enzon's Rule 30(b)(6) witness on the issue of conception, David Filpula, testified that he did not recall Enzon preparing ADI-PEG compounds having carbohydrate or epoxy linking groups (Exhibit 2 at 172:4-183:10).

The evidence relating to conception of the other claim elements also demonstrates fact issues that preclude Enzon's "sole ownership" summary judgment motion. The 738 Patent claims, for example, specify that the PEG component of the recited ADI-PEG have a molecular weight of from about 1,000 to about 40,000. Enzon's evidence, however, indicates that its employees did not conceive this molecular weight range. Indeed, Enzon's invention record refers to PEG groups having molecular weights of 5,000 and 12,000 (Exhibit A to Enzon's letter brief at E016070), and nowhere mentions the use of PEG groups having molecular weights of up to about 40,000. Similarly, although the 738 Patent claims are directed to ADI-PEG compounds in which the ADI component is derived from the microorganisms *mycoplasma hominus* and *mycoplasma arthritides*, Enzon's invention record refers only to compounds in which the ADI component is derived from the microorganism *mycoplasma arginini* (*id.* at E016072).

Thus, the available evidence is inconsistent with Enzon's assertion that its employees conceived all of the claimed inventions, and at the very least demonstrates issues of material fact that preclude summary adjudication that Enzon is entitled to sole ownership of the 738 Patent. Accordingly, Enzon should be denied leave to file its proposed motion.

Although factual disputes exist as to whether or not Enzon employees conceived all of the inventions claimed in the 738 Patent, it is beyond dispute (as noted in Phoenix's summary judgment letter brief) that Dr. Clark conceived claimed inventions after he left Enzon's employ. Thus, because Enzon seeks summary judgment that it is the *sole owner* of the 738 Patent whereas Phoenix seeks summary judgment that it is *at least a co-owner*, the Court should deny Enzon leave to file its motion while granting Phoenix such leave.

The Court Should Deny Enzon Leave To File A Motion Seeking Summary Judgment That Phoenix's Affirmative Defenses Are Insufficient As A Matter Of Law

Enzon also should be denied leave to file its proposed motion for summary judgment on Phoenix's defenses because the few facts that Enzon identifies in its letter brief would not support summary judgment and, moreover, are in error. Enzon, for example, is mistaken with respect to its assertion that summary judgment is warranted because "Phoenix has not ... provide[d] any factual support for its affirmative defenses" (Enzon Letter Brief at 4). Phoenix provided such factual support in response to Enzon's interrogatories inquiring into the basis Phoenix's affirmative defenses (Ex. 3 at 2-6). These facts demonstrate, for example, Enzon's impermissible delay with respect to its unjust enrichment count, and raise fact issues that preclude the summary adjudication that

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Enzon now seeks. Accordingly, the Court should deny Enzon leave to file its proposed motion for summary judgment with respect to Phoenix's affirmative defenses.

Conclusion

Phoenix respectfully requests that the Court deny Enzon leave to file either its proposed motion for summary judgment of sole ownership of the 738 Patent, or its proposed motion for summary judgment on Phoenix's affirmative defenses.

Respectfully submitted,

A handwritten signature in black ink, appearing to read "Richard D. Kirk".

Richard D. Kirk, Esq.

cc: Joseph Lucci, Esq.
Michael Siem, Esq.